

Food and Drug Administration Rockville MD 20857

Re: Maxalt Docket No. 98E-0852

SEP 6 2001

The Honorable Q. Todd Dickinson Director of U.S. Patent and Trademark Office Commissioner for Patents Box Pat. Ext. Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 5,298,520 filed by Merck & Company under 35 U.S.C. § 156. The patent claims the human drug product Maxalt (rizatriptan benzoate), new drug application NDA 20-864.

In the January 27, 2000, issue of the <u>Federal Register</u> (65 Fed. Reg. 4428), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Mane A Axelrad

Associate Director for Policy

Center for Drug Evaluation and Research

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cc:

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